December 19, 2024

Onward Medical Inc.
Nathalie Gilat
Sr. Director Clinical & Regulatory
50 Milk Street
Boston, Massachusetts 02109

Re: DEN240014
Trade/Device Name: ARC$^{EX}$ System
Regulation Number: 21 CFR 890.5851
Regulation Name: Transcutaneous electrical spine stimulator to improve skeletal muscle strength and sensation
Regulatory Class: Class II
Product Code: SDO
Dated: March 28, 2024
Received: March 28, 2024

Dear Nathalie Gilat:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the ARC$^{EX}$ System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The ARC$^{EX}$ System is intended to deliver programmed, transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive).

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ARC$^{EX}$ System, and substantially equivalent devices of this generic type, into Class II under the generic name transcutaneous electrical spine stimulator to improve skeletal muscle strength and sensation.

FDA identifies this generic type of device as:

> **Transcutaneous electrical spine stimulator to improve skeletal muscle strength and sensation**. A transcutaneous electrical spine stimulator to improve skeletal muscle strength and sensation is a device that can be programmed to apply an electrical current via electrodes on a patient's skin over the spine to improve muscle strength and sensation after neurological deficit.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On March 28, 2024, FDA received your De Novo requesting classification of the ARC$^{EX}$ System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ARC$^{EX}$ System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the ARC$^{EX}$ System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks to health are shown in the table below. The identified risks and mitigation measures associated with the device type are summarized in the following table:

| **Risks to Health** | **Mitigation Measures** |
|---|---|
| Ineffective treatment from insufficient stimulation due to device failure, interference with other devices, or user error, leading to worsening condition | Non-clinical performance testing<br>Software verification, validation, and hazard analysis<br>Labeling |
| Adverse tissue reaction | Biocompatibility evaluation<br>Labeling |
| Overstimulation due to device failure, interference with other devices, or user error, leading to skin discomfort, burns, electrical shock, pain at stimulation site, muscle spasms and stiffness | Non-clinical performance testing<br>Electromagnetic compatibility (EMC) testing<br>Electrical, thermal, and mechanical safety testing<br>Software verification, validation, and hazard analysis<br>Labeling |

In combination with the general controls of the FD&C Act, the transcutaneous electrical spine stimulator to improve skeletal muscle strength and sensation is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:
   (i) Characterization of the electrical stimulation parameters, including the following: waveforms; output modes; maximum output voltage and maximum output current; pulse duration; frequency; net charge per pulse; maximum phase charge, maximum current density, maximum average current, and maximum average power density;

(ii) Characterization of the impedance monitoring system; and
(iii) Characterization of electrode performance, including the electrical performance, adhesive integrity, shelf life, reusability, and current distribution of the electrode surface area.

(2) Performance data must demonstrate the electromagnetic compatibility, electrical safety and performance, battery safety, and wireless compatibility of the device.
(3) Software verification, validation and hazard analysis must be performed.
(4) The patient-contacting components of the device must be demonstrated to be biocompatible.
(5) Labeling must include:
(i) Summaries of electrical stimulation parameters;
(ii) Instructions for user management of the device in the event of adverse effects;
(iii) A contraindication for patients with active implantable devices or wearable defibrillators;
(iv) Information on the typical sensations experienced during treatment;
(v) Instructions for accurate placement of the device on the patient; and
(vi) Cleaning instructions.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the transcutaneous electrical spine stimulator to improve skeletal muscle strength and sensation they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that

the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Ambarish Pawar, PhD at Ambarish.Pawar@fda.hhs.gov.

Sincerely,

David P. Mc Mullen -S

Digitally signed by David P. Mc Mullen -S
Date: 2024.12.19 09:02:55 -05'00'

David McMullen, MD
Director
OHT5: Office of Neurological and
Physical Medicine Devices
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